K002848

MAY 2 4 2001

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
Vice President, Regulatory Affairs and Quality Assurance
Telephone: (972) 801-9854
Fax: (972) 801-9859

Date Prepared:

May 23, 2001

Product Name:

Common Name: SpO2 Sensor (accessory to pulse oximeter)
Trade Name(s): SpO2 Wrap Sensor

Predicate Device:

This product is a modification to the Epic 800 Series Wrap SpO2 sensor marketed under 510(k) # K992211 to expand indications for use to the neonatal population.

Description:

The SpO_2 Wrap Sensor is an electro-optical sensor that functions without skin penetration, electrical contact, or heat transfer. It is an accessory to compatible SpO_2 oximeters. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector.

The LED's and photodiode are contained in a flexible, L-shaped housing that is positioned over the desired patient digit and secured in place with a fabric wrap.

The sensor cable is 3-12 feet in length and is terminated in DB-9 and Hypertronics style connectors.

Intended Use:

The SpO_2 Wrap Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients from neonatal to adult.

Comparison to Predicate Device:

The SpO_2 Wrap Sensor is identical to the predicate device, with the addition of neonatal indications for use in the labeling claims.

Performance Data & Conclusions:

Our risk analysis of this change raised several new concerns relating to product use on a neonatal population: 1) possible effects of fetal hemoglobin on accuracy results, 2) possible material effects on delicate neonatal skin, and 3) possible light interference due to skin translucency, which may prevent the oximeter from detecting a signal.

We have included in this submission several published articles evaluating the effects of fetal hemoglobin on the accuracy of noninvasive pulse oximeters. These articles demonstrate that the presence of fetal hemoglobin does not affect pulse oximeter accuracy. Limited clinical data also demonstrate that the Epic Wrap Sensor continues to meet established accuracy claims when used in the neonatal population. In addition, Epic included information in its labeling to allow for differences in hemoglobin saturation vs. optical absorption characteristics, and for unmeasured variables for which there are no data (tissue optical scattering characteristics, venous flow waveform, arterial waveform profile, and possible other considerations).

All patient-contacting materials are identical to the predicate device, and meet biocompatibility testing requirements of EN 30993-1/ISO 10993-1. Epic's design validation study included a user evaluation of patient skin integrity after use of the Epic Wrap Sensor, which found no adverse reaction among the neonatal patients evaluated.

Epic's design validation also included a user evaluation with regard to overall performance, including the oximeter's recognition of the signal when the sensor was applied to translucent neonatal skin. No difficulties were reported by the users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2001

Ms. Krista Oakes
Vice President, Regulatory Affairs and Quality Assurance
Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Re: K002848
SpO_2 Wrap Sensor
Regulation Number: 870.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: April 3, 2001
Received: April 6, 2001

Dear Ms. Oakes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K002848
Device Name: SpO_2 Wrap Sensor

Indications for Use:
The SpO_2 Wrap Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patient populations ranging from neonatal to adult.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K002848